Problems with Tobacco Products? Tell FDA

Are you using a tobacco product that you believe is defective or is causing an unexpected health problem? Are you using a tobacco product that has a strange taste or smell?

The Food and Drug Administration (FDA) wants to hear from you and has a new online tool you can use to report your problem.

The Department of Health and Human Services' Safety Reporting Portal (SRP) (*www.safetyreporting.hhs.gov*) has been revised to add a new category for tobacco products. This update provides a standardized way for consumers and health care professionals to let FDA know when they suspect that there is an unexpected health or safety issue with a specific tobacco product.

Until now, consumers reported problems with tobacco products to FDA through MedWatch, the FDA Safety Information and Adverse Event Reporting Program, a system that does not ask questions specific to tobacco products.

"There is no known safe tobacco product, but FDA can play a role in helping prevent certain unexpected health consequences from tobacco products, such as those that occur from defective tobacco products, or health or safety problems beyond those normally associated with tobacco product use," says Ii-Lun Chen, M.D., medical branch chief in the Office of Science at FDA's Center for Tobacco Products.

What to Report

As part of its charge to protect public health and reduce harm from tobacco products, FDA is interested in reports from consumers about tobacco products that are damaged, defective or contaminated, such as cigarettes containing mold. It could also be that a tobacco product just smells or tastes wrong.

FDA also wants to know if tobacco product users have experienced an unexpected health or other safety problem that they believe has been caused by use of a particular tobacco product. These could include reports of fire caused by tobacco product use, burns or other injuries, accidental or unintended exposure of children, allergic reactions, poisonings and other toxicities, or an unusual reaction in a long-time user.

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When filling out the online fields in the SRP, health professionals and consumers can report a number of potential types of product and health problems, such as:

Product problems:
- Problems using the tobacco product
- Problems with labeling, packaging or instructions for use
- Tobacco product mix-ups
- Quality problems, such as unexpected appearance, smell or taste; foreign objects in the product or other possible contamination; or a defective or malfunctioning product.

Health problems:
- Unusual health problems with any category of tobacco product, such as symptoms that are unusual in their type or severity, injuries or burns, or allergic reactions.
- Pregnancy or fertility problems, harm to children or non-users, including by accidental ingestion or exposure.

Reports may be submitted for tobacco products including cigarettes, tobacco used for roll-your own cigarettes, other smoking tobacco, cigars, smokeless tobacco, electronic cigarettes or any other product made or derived from tobacco that is intended for human consumption and is not regulated by FDA as a drug or medical device.

Consumers and health professionals who want to report problems with nicotine replacement products that have FDA-approved therapeutic claims (such as that they help smokers to quit) should continue to do so through MedWatch.

What FDA Does with Reports

FDA is interested in building a comprehensive tobacco regulation program that ensures all tobacco products have an appropriate level of regulatory oversight. One part of this process includes understanding the types of adverse events being experienced by consumers of tobacco products.

FDA currently regulates cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. However, FDA can accept voluntarily submitted information related to all tobacco products and how they are functioning in the marketplace under the Food, Drug and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act. To that end, FDA is also encouraging reports of problems associated with new types of tobacco products, such as electronic cigarettes and hookah.

FDA will review and evaluate reports and may take steps, as appropriate, to ensure that the public health is protected. The agency will not routinely contact people who submit reports to the SRP to discuss their reports or the outcome of FDA review. However, if a person provides contact information, FDA may sometimes request additional information or tobacco product samples, if available. FDA reviews and archives submitted reports, and lack of contact does not mean that the agency has not reviewed your report.

FDA cannot provide individual advice to consumers. If you have an issue that requires medical attention, you should contact your health care professional.

Consumers who are unable to submit reports using the electronic system can contact the Center for Tobacco Products at 1-877-CTP-1373 or *AskCTP@fda.hhs.gov.*

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